

the limitations on exemptions in subpart E of part 20 of this chapter.

[39 FR 44657, Dec. 24, 1974, as amended at 42 FR 15676, Mar. 22, 1977; 46 FR 38074, July 24, 1981]

§ 730.8 Misbranding by reference to filing; filing does not constitute an admission.

(a) The filing of an experience report does not in any way constitute approval of the firm or the cosmetic product by the Food and Drug Administration. Any representation in labeling or advertising that creates an impression of official approval because of such filing will be considered misleading.

(b) The filing of an experience report does not in any way constitute an admission by the person filing the report that the alleged experience was the result of an ingredient or ingredients in the cosmetic product, or of any other fact.

PART 740—COSMETIC PRODUCT WARNING STATEMENTS

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740.18 Coal tar hair dyes posing a risk of cancer.

AUTHORITY: Secs. 201, 301, 502, 505, 601, 602, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 352, 355, 361, 362, 371, 374).

Subpart A—General

§ 740.1 Establishment of warning statements.

(a) The label of a cosmetic product shall bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with the product.

(b) The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has submitted a petition, may publish a proposal to establish or amend, under subpart B of this part, a regulation prescribing a warning for a cosmetic. Any such petition shall include an adequate factual basis to support the petition, shall be in the form set forth in part 10 of this chapter, and will be published for comment if it contains reasonable grounds for the proposed regulation.

[40 FR 8917, Mar. 3, 1975, as amended at 42 FR 15676, Mar. 22, 1977]

§ 740.2 Conspicuousness of warning statements.

(a) A warning statement shall appear on the label prominently and conspicuously as compared to other words, statements, designs, or devices and in bold type on contrasting background to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use, but in no case may the letters and/or numbers be less than $\frac{1}{16}$ inch in height, unless an exemption pursuant to paragraph (b) of this section is established.

(b) If the label of any cosmetic package is too small to accommodate the information as required by this section, the Commissioner may establish by regulation an acceptable alternative method, e.g., type size smaller than $\frac{1}{16}$ inch in height. A petition requesting such a regulation, as an amendment to this section, shall be submitted to the Dockets Management Branch in the form established in part 10 of this chapter.

[40 FR 8917, Mar. 3, 1975, as amended at 42 FR 15676, Mar. 22, 1977]

Subpart B—Warning Statements

§ 740.10 Labeling of cosmetic products for which adequate substantiation of safety has not been obtained.

(a) Each ingredient used in a cosmetic product and each finished cosmetic product shall be adequately substantiated for safety prior to marketing. Any such ingredient or product whose safety is not adequately substantiated prior to marketing is